K042929

DEC - 6 2004

510(k) SUMMARY

1. Submitter

1) Name	KURARAY MEDICAL INC.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-8622, Japan
3) Contact person	Masaya Sasaki Dental Material Division
4) Date	October 18, 2004
5) Contact person in U.S.A.	Koji Nishida Kuraray America, Inc. 101 East 52nd Street, 26th Floor, New York, NY 10022 Telephone : (212)-986-2230 (Ext.115) Facsimile : (212)-867-3543

2. Name of Device

1) Proprietary Name	ESTENIA C&B
2) Classification Name	Tooth shade resin material (21CFR 872.3690)
3) Common/Usual Name	Polymer-based crown and bridge material

3. Predicate device:

The predicate products are;

a) Tooth shade resin material

1. ESTENIA	by Kuraray Medical Inc.	(K012707)
2. EPRICORD	by Kuraray Medical Inc.	(K033267)
3. CHROMA ZONE COLOR STAIN	by Kuraray Medical Inc.	(K012737)
4. SINFONY	by ESPE DENTAL AG	(K992645)
5. TARGIS SYSTEM	by IVOCLAR NORTH AMERICA, INC.	(K962878)
6. ARTGLASS & KEVLOC	by HERAEUS KULZER, INC.	(K954115)
7. SOLIDEX	by SHOFU DENTAL CORP.	(K972292)
8. VENUS UNIVERSAL LIGHT CURING COMPOSITE	by HERAEUS KULZER, INC.	(K020131)
9. FIBREKOR	by JENERIC/PENTRON, INC.	(K964578)

b) Other dental materials

1. CLEARFIL SE BOND	by Kuraray Medical Inc.	(K012442)
2. CONNECT	by SYBRON DENTAL SPECIALTIES, INC.	(K954689)

4. Device description and intended use

This device is a polymer-based material, used for fabricating prosthetic appliance such as facing cast crowns, facing cast bridges, jacket crowns, inlays, onlays or bridges with frameworks, and for repair of those prosthetic appliances made of resin-based crown and bridge materials or porcelain.

5. Statement of the technological characteristics and safety

Chemical ingredients, design, physical and mechanical properties, and safety are same as predicate devices in the USA.

The physical and mechanical properties of ESTENIA C&B are verified by evaluation test based on ISO 10477. Safety is also verified because all chemical ingredients are used in legally marketed predicate devices.

Therefore this device is safe, effective, and substantially equivalent with predicated devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 6 2004

Kuraray Medical, Incorporated
C/O Ms. Koji Nishida
Kuraray America, Incorporated
101 East 52nd Street, 26th Floor
New York, New York 10022

Re: K042929
Trade/Device Names: Estenia™ C&B
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Codes: EBF and EBG
Dated: October 18, 2004
Received: October 27, 2004

Dear Ms. Nishida:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

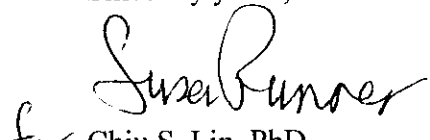
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042929

Indications for Use

ESTENIA C&B is indicated for the following applications for the restoring crowns and defects.

1) Facing cast crowns and facing cast bridges
2) Jacket crowns
3) Inlays and onlays
4) Bridges with frameworks

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Part 21 CFR 801.109)

(Optional Format 1-2-96)

Kevin Mulley for MSP
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042929